

## REMARKS

### A. Drawing Objection

The Office Action objected the drawings under 37 CFR 1.84(p)(5) for not including the following reference character(s) mentioned in the description: element 1703. Applicants would like to direct the Examiner's attention to the amended first paragraph of page 29 which now states "...Tissue connector assembly 1701 includes a bridge clip 1707 having a pair of clips or fasteners 1703 and a connecting bridge 1705. Each of the pair of clip and components corresponding to each of the pair of clips is denoted with a prime or double-prime. Thus, for example, the pair of clips 1703 includes a first clip 1703' and a second clip 1703''..." Corrected figures 17 and 18 now include clips 1703. Applicant's would also like to direct the Examiner's attention to the amended second paragraph of page 36 which now states "...Fig. 19B shows bridge clip 1707 in the closed configuration as it appears after joining vessels 1901 and 1903. Each fastener 1703' and 1703'' is positioned, prior to closing, from the outer to inner surface of 1901 and through the inner to outer surface of target vessel 1903..." Corrected figure 19B now includes clips 1703. Finally, applicant's would like to direct the Examiner's attention to the third paragraph of page 36 which states "...A procedure that may be used to clip the tissue as in Fig. 20 is to aligning tissue edges 2007 and 2009 of tissues 2001 and 2003, pierce tissue 2001 and 2003 with piercing members 16 to create piercings 2005, and then releasing clips 1703. When this is done, the bridge portion 1705 sits on an outer surface to tissue 2001 while the clips 1703 go through the piercings 2005 and wrap around the edges 2007 and 2009 towards tissue 2001..." Previously submitted figure 20B included clips 1703.

Applicant's herein submit a proposed drawing correction to Figures 17, 18 and 19B. This drawing correction merely conforms the drawings to the originally filed written specification. Thus, no new matter is submitted. A complete set of formal drawings is also submitted by applicants.

B. Claim Rejections Under 35 U.S.C. §102

The Office Action rejected claims 1-14, 20-23 and 31-35 under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 5,941,888 (“Wallace et al.”). This rejection is respectfully traversed.

The Wallace et al. reference discloses an occlusion device delivered to a desired site in a mammal to facilitate the formation of mechanical blockage or thrombi in arteries, veins, aneurysms, vascular malformations and arteriovenous fistulas (see col. 1, lines 5-9). More specifically, the occlusion device comprises one or more vaso-occlusive members that can be sequentially and selectively delivered by electrolytic detachment of a sacrificial link to a desired thrombus formation site (see col. 1, lines 9-12). The sacrificial link between the vaso-occlusive members 102 and 104 is an electrolytically disintegratable link 106 (see col. 5, lines 55-56). Central to Wallace et al. invention is electrical isolation of vaso-occlusive members 102 and 104 by electrically insulative joint 108, which joins the proximal end of vaso-occlusive member 102 to link 106 (see col. 6, lines 5-8). Electrically conductive joint 110 joins the distal end of vaso-occlusive member 104 to link 106 (see col. 7, lines 54-57). During use, the occlusion device is designed so a physician can selectively deploy one or more vaso-occlusive members into an aneurysm as required until the aneurysm has been sufficiently filled (see col. 10, lines 64-67). An electric current is then applied to the device to form a thrombus within the aneurysm (see col. 11, lines 27-30). After the thrombus has been formed and the aneurysm occluded, the electrolytically disintegratable link is electrolytically disintegrated, thereby detaching the desired number of vaso-occlusive devices (see col. 11, lines 33-35).

The dictionary definition of the term “aneurysm” is a “circumscribed dilation of an artery or cardiac chamber...usually due to an acquired or congenital weakness of the wall of the artery or chamber” Stedman’s Medical Dictionary, 27<sup>th</sup> Edition, page 79. The dictionary definition of the term “thrombus” (or pl. “thrombi”) is “a clot in the cardiovascular system” that “may be occlusive” Stedman’s Medical Dictionary, 27<sup>th</sup> Edition, page 1832. Wallace et al. discloses a device for causing the clotting of blood within a desired site within the vascular system of a patient. Wallace et al. never discloses a device or method for connecting two vessels or tissues together.

A rejection based on anticipation under 35 U.S.C. 102 requires all of the elements recited in the claims of the invention to be found within the four corners of the cited reference. Independent claims 1, 20 and 31 were amended without prejudice. Amended independent claims 1, 20 and 31 and dependent claims 2-14, 21-23 and 32-35 depending from claims 1, 20 and 31, respectively, now include the limitation that the surgical fastener or apparatus comprises two clips adapted to attach tissues, as recited in claims 1 and 20 or that the surgical clip apparatus is adapted to attach tissues, as recited in claim 31. These limitations are never disclosed in the Wallace et al. reference, thus the U.S.C. 102 rejection should be withdrawn. In fact, Wallace et al. never shows or describes any sort of tissue connector for attaching tissues. Instead, Wallace et al. discloses a thrombus-forming device having vaso-occlusive members used to occlude sites within vessels such as aneurysms.

C. Claim Rejections Under 35 U.S.C. §103

The Office Action rejected claims 15-19, 24-26 and 36-38 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 5,645,568 ("Chervitz et al."). This rejection is respectfully traversed.

The Chervitz et al. reference discloses an enlarged area, pledget, bump, or the like, formed in a suture body, that, when the enlarged area is fitted into a hole formed by the suture, provides a tight fit in the hole (see col.1, lines 21-25). Pledget 13 can have a round 13a, elliptical 13b, square 13c, triangular 13d, or the like, cross section and is of a diameter to be snugly contained within the suture body 11 (see col. 3, lines 12-15). Where the suture body 11 is to be threaded through a plurality of holes, an appropriate number of pledgets 13 can be arranged at spaced intervals in the suture body (see Fig. 3 and col. 3, lines 24-28). Pledget 13 is installed in the suture body 11, the pledget can be maintained onto a cord or string 14, with the suture body 11 formed thereover to encapsulate both the cord or string 14 and the pledget 13 (see col. 3, lines 29-35).

Amended independent claims 1, 24 and 36 and dependent claims 15-19, 25-26 and 37-38 depending from claims 1, 24 and 36, respectively, now include the limitation of a surgical fastener or apparatus comprising two clips adapted to attach tissues, as recited in claims 1 and 24 or a surgical clip apparatus adapted to attach tissues, as recited

in claim 36. The Chervitz et al. reference does not provide any motivation, suggestion or teachings regarding surgical clips. Instead, Wallace et al. discloses a suture having one or more enlarged areas or pledgets for tightly fitting within the hole or holes formed by the needle of the suture passing through bone, tendon, ligament, or the like, the pledgets thereby preventing the suture from moving within the hole (see col. 1, lines 11-27).

Claims 15-19 and 24-26 further include the limitation of a self-closing clip. The Chervitz et al. reference does not provide any motivation, suggestion or teachings regarding self-closing surgical clips. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination, therefore the rejection of amended claims 15-19 and 24-26 as being unpatentable over Chervitz et al. should be withdrawn.

Claim 36-38 further includes the limitation that the surgical clip comprises an elongated member, a pair of coils surrounding at least a portion of said elongated member, said pair of coils being serially arranged and spaced from one another along said elongated member, said elongated member being shape memory material and having an unbiased shape, which includes a plurality of loops, and a biased shape, said elongated member tending to move toward said unbiased shape from said biased shape. The Chervitz et al. reference does not provide any motivation, suggestion or teachings regarding a surgical clip tending to move toward an unbiased shape from a biased shape. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination, therefore the rejection of amended claims 36-38 as being unpatentable over Chervitz et al. should be withdrawn.

#### D. Nonstatutory Double Patenting Rejection

1. The Office Action provisionally rejected claims 1-26 and 31-38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 09/828,335. Applicants respectfully submit that the claims of the present case are not obvious as proposed by the Examiner and reserves the right to argue this matter in the future. However, solely in an effort to expedite prosecution of this case and not as an admission as to the obviousness of the

claims, a terminal disclaimer has been filed. Therefore, the rejection of claims 1-26 and 31-38 under the judicially created doctrine of obviousness-type double patenting is now moot.

2. The Office Action rejected claims 31-38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 8, 41, 45 and 46 of U.S. Patent No. 6,641,593. Applicants respectfully submit that the claims of the present case are not obvious as proposed by the Examiner and reserves the right to argue this matter in the future. However, solely in an effort to expedite prosecution of this case and not as an admission as to the obviousness of the claims, a terminal disclaimer has been filed. Therefore, the rejection of claims 31-38 under the judicially created doctrine of obviousness-type double patenting is now moot.

3. The Office Action provisionally rejected claims 31-38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 34, 55-57, 61 and 91-93 of U.S. Patent No. 6,613,059. Applicants respectfully submit that the claims of the present case are not obvious as proposed by the Examiner and reserves the right to argue this matter in the future. However, solely in an effort to expedite prosecution of this case and not as an admission as to the obviousness of the claims, a terminal disclaimer has been filed. Therefore, the rejection of claims 31-38 under the judicially created doctrine of obviousness-type double patenting is now moot.

Support for this amendment is clearly found in the application as originally filed. No new matter is presented.

Examination and reconsideration of the application as amended is requested. After amending and canceling claims as set forth above, claims 1-26 and 31-38 remain pending in the application and are now believed to be in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

A terminal disclaimer accompanies this amendment. Please charge the fee for submission of the terminal disclaimer to Deposit Account No. 13-2546.

Applicant respectfully petitions the Commissioner for Patents to extend the time for response to the Office Action dated July 26, 2004 for two (2) month from October 26, 2004 to December 26, 2004. Please charge the fee provided in:

X 37 C.F.R. 1.17(a)(2) Extension for response within second month

to Deposit Account No. 13-2546.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned agent at 763-391-9867.

Please charge any additional required fees or credit any overpayment to  
Deposit Account No. 13-2546.

Date December 9, 2004

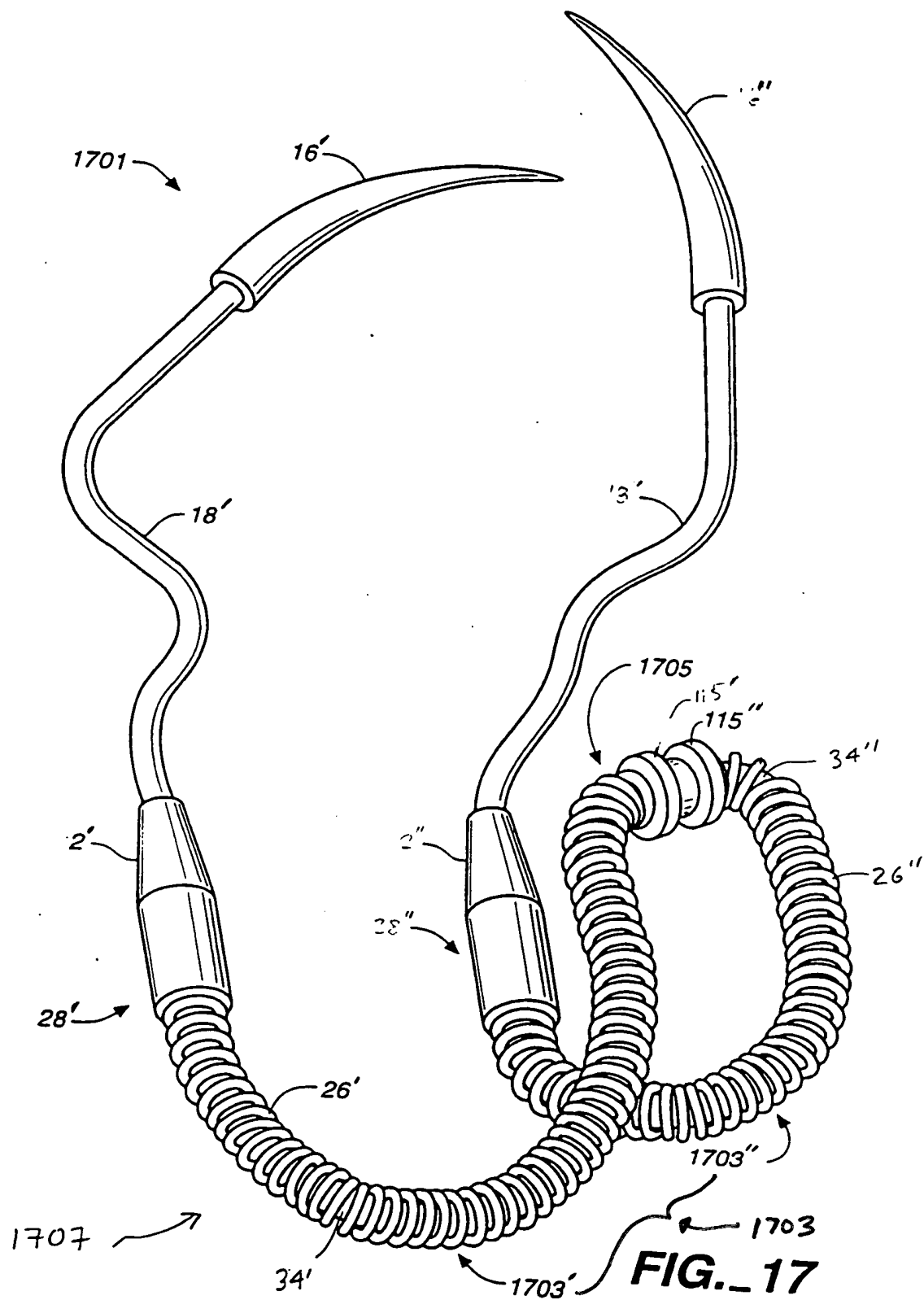
By  \_\_\_\_\_

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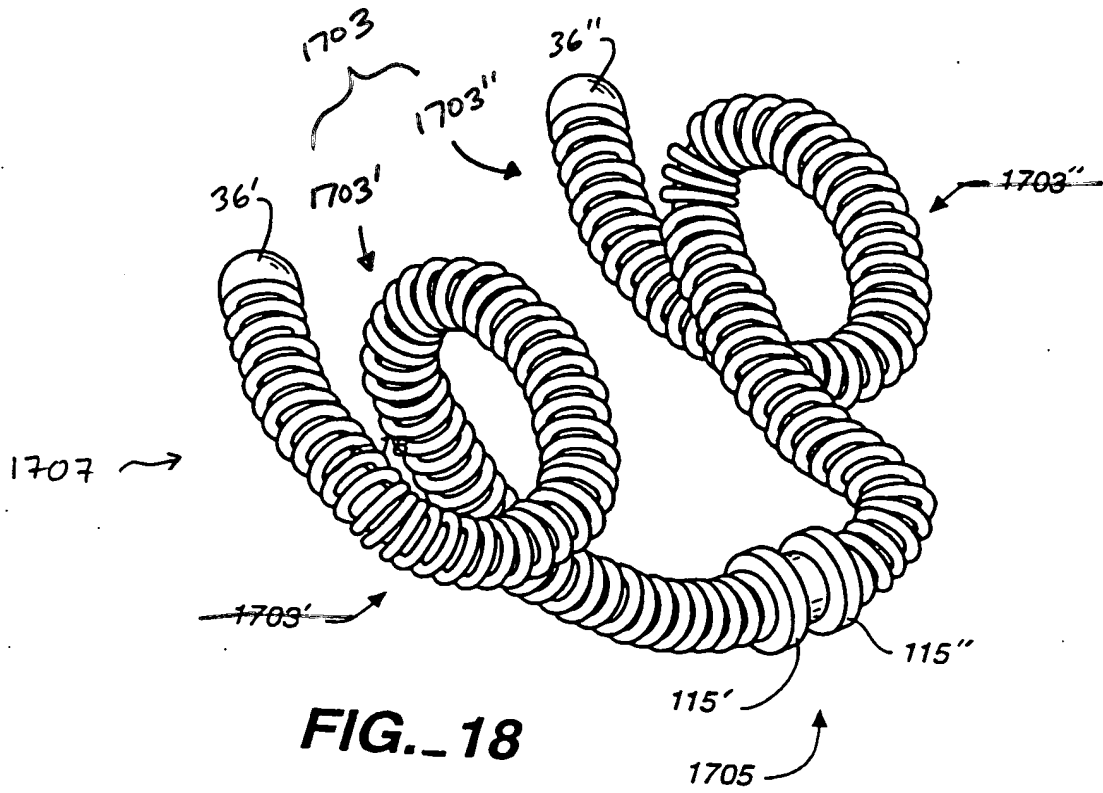
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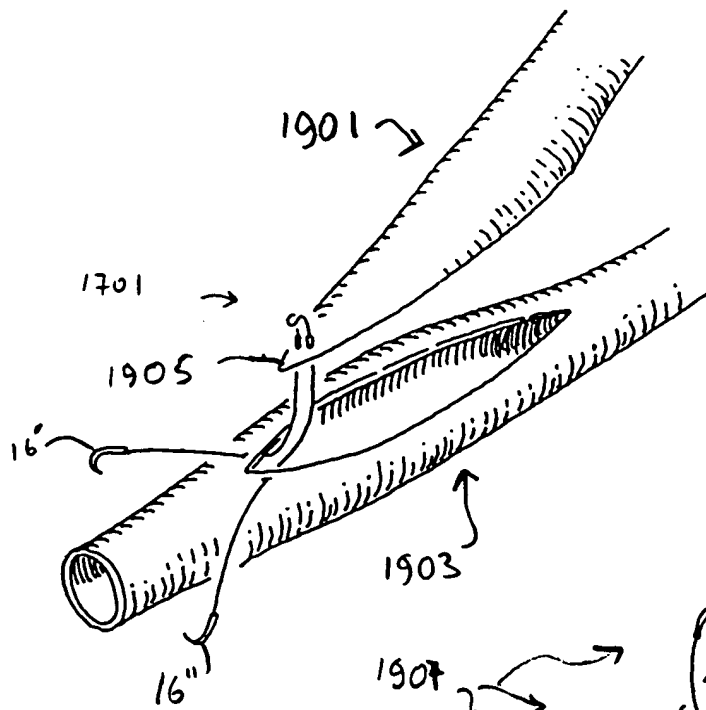


**FIG. 17**

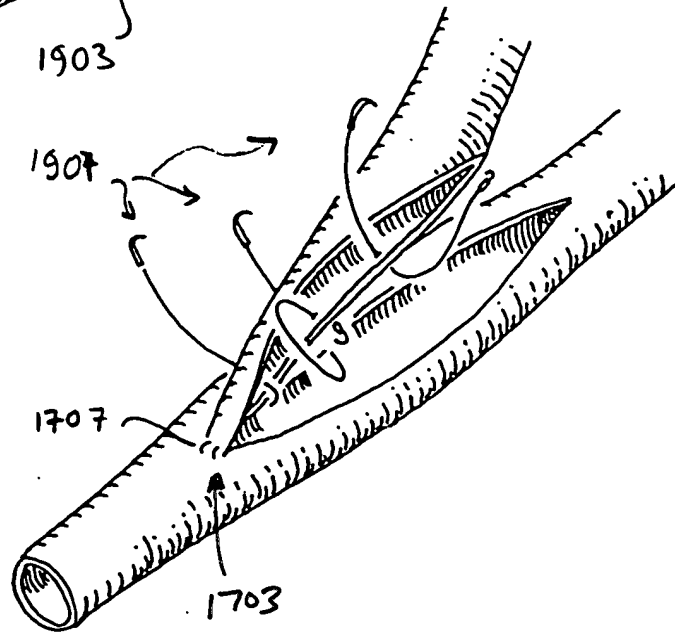
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A



B



C

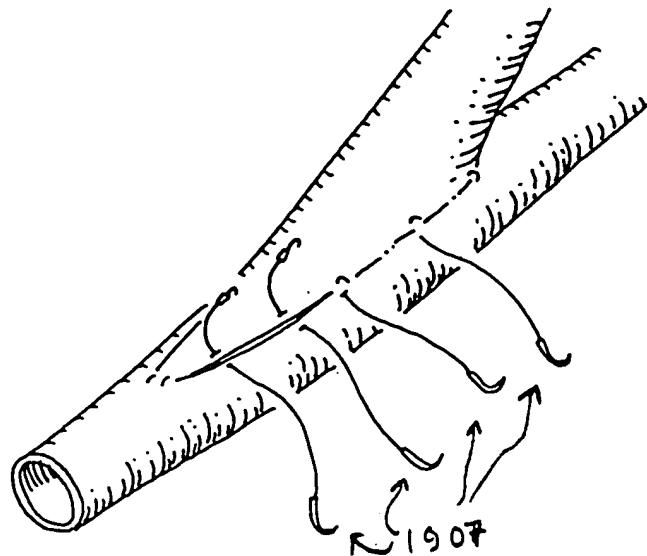


FIG 19